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EXAMINER	
BLANCO, JAVIER G	
ART UNIT	**PAPER NUMBER**
3738	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/19/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/757,819	MOLZ, FRED J.	
	Examiner	Art Unit	
	Javier G. Blanco	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 January 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-62* is/are pending in the application.

4a) Of the above claim(s) *4,5,16 and 40-62* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,6-15 and 17-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/15/2004; 8/22/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of GROUP/INVENTION I (embodied in claims 1-39) in the reply filed on January 25, 2007 is acknowledged.

2. Applicant's election with traverse of **Implant/Device/Interlock**: Species B (Figures 3 and 4), **Pair of side surfaces:** Species A (parallel to one another), and **Interlock or spinal implant:** Species A (comprising at least one aperture/opening) in the reply filed on January 25, 2007 is acknowledged. The traversal is on the ground(s) that "*indicated Species A and B under Iimplant/Device/Interlock are both directed to the same species of the invention*". This is found persuasive, therefore the requirement (based on the **Implant/Device/Interlock** species indicated by the Examiner) is hereby withdrawn.

The requirement is still deemed proper and is therefore made FINAL.

3. Claims 4, 5, 16, and 40-62 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected GROUP/INVENTION and Species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on January 25, 2007.

Claim Objections

4. Claim 27 is objected to because of the following informalities:

a. Regarding claim 27, please substitute "claim 25" (see line 1) with --claim 26--. Otherwise the limitations recited therein will lack antecedent basis. Appropriate correction is required.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-3, 6-15, 19-23, 25-31, 33, and 35-39 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Crozet et al. (US 6,375,683 B1).

Referring to Figures 1-8, Crozet et al. disclose a spinal construct comprising:

(i) A spinal implant (Figure 8: element 30; Figures 1-7: elements 30a, 30b) extending along a longitudinal axis and having a first transverse dimension and a second transverse dimension greater than said first transverse dimension and corresponding to a select height of an intervertebral space (see column 4, lines 45-50 and lines 54-67); and

(ii) An elongate member (Figure 8: element 100 and element 200; Figures 1-7: bearing elements 20a, 20b and intermediate plate 11).

As shown in Figures 1-8 (see column 4, lines 45-50 and lines 54-67), the implant includes a first pair of side surfaces spaced apart and arranged generally opposite one another to define said first transverse dimension, and a second pair of side surfaces spaced apart and arranged generally opposite one another to define said second transverse dimension, wherein the first transverse dimension is substantially perpendicular to the second transverse dimension. Also, the implant has a rectangular transverse cross section, and includes rounded corners to facilitate rotation. The spinal construct further includes an interlock, including at least one aperture (bores 15 and/or bore(s) 34) and at least one projection (screw(s) 40 and nut(s) 50). As

an alternative interpretation, the interlock could also be the frictional interaction/engagement between the implant and the elongate member (see column 5, lines 27-33), wherein surfaces 32 and 32' or 33 and 33' are the projections, grooves 12a and 22 or 12b and 22 are the apertures, and screw 40 (or screws 40) is the fastener. An axially facing portion of the implant defines at least two tool-engaging elements (sockets 35) *sized and configured for engagement* with corresponding portions of a manipulation tool (see column 4, lines 58-61). The elongate member defines a pair of arcuate slots (24 and/or 14) positioned diametrically opposite one another relative to the longitudinal axis.

Note: Claims directed to apparatus must be distinguished from the prior art in terms of structure rather than function. *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA1959). "[A]pparatus claims cover what a device is, not what a device does." *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990). Expressions relating the apparatus to contents thereof during an intended operation are of no significance in determining patentability of the apparatus claim. *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969).

7. Claims 1, 9, 10-12, 25, 29, 30, 31, and 35-37 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Rezaian (US 4,401,112; cited in Applicant's IDS).

Referring to Figures 1-4, Rezaian discloses a spinal construct comprising:

(i) A spinal implant (Figures 1 and 4) extending along a longitudinal axis and having a first transverse dimension and a second transverse dimension greater than said first transverse

dimension and corresponding to a select height of an intervertebral space (see column 2, lines 11-17); and

(ii) An elongate member (plate 11) engaged with said implant (see Figure 4).

As seen in Figure 4, the construct further comprises an interlock (arcuate slot 12 of plate 11, threaded bore 9 of the implant, and fastener 13). The means for transitioning the implant from said first transverse dimension to said second transverse dimension is a tool (see column 2, lines 10-17).

Note: Claims directed to apparatus must be distinguished from the prior art in terms of structure rather than function. *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA1959). "[A]pparatus claims cover what a device is, not what a device does." *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990). Expressions relating the apparatus to contents thereof during an intended operation are of no significance in determining patentability of the apparatus claim. *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969).

8. Claims 1-3, 6-12, 23-31, and 33-38 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Dixon et al. (US PG Pub No 2002/0107519 A1).

Referring to Figures 1-10, Dixon et al. disclose a spinal construct comprising:

(i) A spinal implant (plates 31 and/or dowel 53) extending along a longitudinal axis and having a first transverse dimension and a second transverse dimension greater than said first transverse dimension and corresponding to a select height of an intervertebral space (Figures 4 and 5; see paragraph 0030 and paragraph 0041); and

(ii) An elongate member (flange 33; flange 33 and tube 34).

As shown in Figures 3a-3d, the implant includes a first pair of side surfaces spaced apart and arranged generally opposite one another to define said first transverse dimension, and a second pair of side surfaces spaced apart and arranged generally opposite one another to define said second transverse dimension, wherein the first transverse dimension is substantially perpendicular to the second transverse dimension. Also, the implant includes a substantially rectangular transverse cross section and rounded corners to facilitate rotation. The spinal construct further includes an interlock (see Figure 2), including at least one aperture (flange slots 32 or arcuate flanges 46) and at least one projection (an end of the implant is broadly interpreted as projecting). The elongate member comprises top and bottom openings 37 to accept fasteners (screws 36). A tool (see Figure 5) is used to rotate the implant from said first transverse dimension to said second transverse dimension.

Note: Claims directed to apparatus must be distinguished from the prior art in terms of structure rather than function. *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA1959). "[A]pparatus claims cover what a device is, not what a device does." *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990). Expressions relating the apparatus to contents thereof during an intended operation are of no significance in determining patentability of the apparatus claim. *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969).

9. Claims 1, 9-12, 19, 20, 24, 25, 29-31, and 34-38 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Day et al. (US 4,892,545 A).

Referring to Figures 1-3, Day et al. disclose a spinal construct comprising:

(i) A spinal implant (pins 16 + cylindrical portion of body 10) extending along a longitudinal axis and having a first transverse dimension and a second transverse dimension greater than said first transverse dimension and corresponding to a select height of an intervertebral space (compare Figure 2 to Figure 3; see column 3, lines 6-33); and

(ii) An elongate member (elongate plate including flanges 26).

Tool 40 (see Figure 2) having prongs 42 engages tool engaging elements 18 of the implant (see column 3, lines 6-19). The spinal construct further includes an interlock, including at least one aperture (channels/sockets 18) and at least one projection (ribs 24 of locking means 22) (see column 3, lines 21-33). As an alternative interpretation, the interlock could also be the frictional interaction/engagement between the implant and the elongate member. The elongate member comprises top and bottom openings 28 to accept fasteners (screws 27).

Note: Claims directed to apparatus must be distinguished from the prior art in terms of structure rather than function. *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA1959). "[A]pparatus claims cover what a device is, not what a device does." *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990). Expressions relating the apparatus to contents thereof during an intended operation are of no significance in determining patentability of the apparatus claim. *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969).

10. Claims 1, 9-12, 24, 25, 29-31, and 34-38 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Steffee (US 4,611,581 A).

Referring to Figures 12-14, Steffee discloses a spinal construct comprising:

(i) A spinal implant (implant 122) extending along a longitudinal axis and having a first transverse dimension and a second transverse dimension greater than said first transverse dimension and corresponding to a select height of an intervertebral space (compare Figure 12 to Figure 13; see column 6, lines 9-48); and

(ii) An elongate member (plate 30 and/or externally threaded member 152), wherein said implant is rotatably engaged with said elongated member. The interlock is the relationship between threads of bore 132 (which threads include ridges/projections and grooves/apertures) and threads of member 152 (which threads include ridges/projections and grooves/apertures). Plate 30 includes openings 52 at first and second end portions.

Note: Claims directed to apparatus must be distinguished from the prior art in terms of structure rather than function. *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA1959). "[A]pparatus claims cover what a device is, not what a device does." *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990). Expressions relating the apparatus to contents thereof during an intended operation are of no significance in determining patentability of the apparatus claim. *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969).

11. Claims 1-3, 6-12, 15, 17-23, 25-32, and 35-40 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Rinner (US 5,683,394 A).

Referring to Figures 1-6, Rinner discloses a spinal construct comprising:

(i) A spinal implant (Figures 1-3: implant 2; Figures 5 and 6: implant 402) extending along a longitudinal axis and having a first transverse dimension and a second transverse dimension greater than said first transverse dimension and corresponding to a select height of an intervertebral space (see column 3, lines 36-44; column 5, lines 34-39); and

(ii) An elongate member (Figures 1-3: member 3; Figures 5 and 6: member 301), wherein said implant is rotatably engaged with said elongated member (see column 3, lines 36-44; column 5, lines 34-39).

As shown in Figures 1 and 2), the implant includes a first pair of side surfaces spaced apart and arranged generally opposite one another to define said first transverse dimension, and a second pair of side surfaces spaced apart and arranged generally opposite one another to define said second transverse dimension, wherein the first transverse dimension is substantially perpendicular to the second transverse dimension. Also, the implant has a rectangular transverse cross section, and includes rounded corners to facilitate rotation. The spinal construct further includes an interlock (see column 3, lines 50-57; column 5, lines 38-46), including at least one aperture (Figures 1-3: detent notches 10; Figures 5 and 6: detent notches 310) and at least one projection (Figures 1-3: detent tabs 110; Figures 5 and 6: detent tabs 410). As an alternative interpretation, the interlock could also be the frictional interaction/engagement between the implant and the elongate member. An axially facing portion of the implant defines at least two tool-engaging elements (Figures 1-3: positioning holes 114; Figures 5 and 6: positioning holes 414) *sized and configured for engagement* with prongs of a manipulation tool (see column 3, lines 61-66; column 5, lines 46-50). The elongate member defines a pair of arcuate slots (arcuate slots 9) positioned diametrically opposite one another relative to the longitudinal axis. The

implant will accept bone growth promoting material (material 21), therefore (as part of the construct) being used as a fusion cage (each of implant 2 and implant 402 comprise a portion 105, 405 defining a small chamber).

Note: Claims directed to apparatus must be distinguished from the prior art in terms of structure rather than function. *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA1959). "[A]pparatus claims cover what a device is, not what a device does." *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990). Expressions relating the apparatus to contents thereof during an intended operation are of no significance in determining patentability of the apparatus claim. *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Javier G. Blanco whose telephone number is 571-272-4747. The examiner can normally be reached on M-F (9:30 a.m.-7:00 p.m.), first Friday of the bi-week off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone numbers for the organization where this application or proceeding is assigned is 571-273-8300 for regular communications and After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Javier G. Blanco

April 14, 2007

David H. Willse
Primary Examiner